K061731

# 510(k) Special Summary Medgraphics Ultima System

SEP - 6 2006

Date of Summary

June 19, 2006

Company Name

Medical Graphics Corporation

350 Oak Grove Parkway

St. Paul, MN 55127

Contact Name

Lynn Brosious

Classification name:

73BZLOxygen Uptake

Computer

Product Name:

Ultima System

CFR section:

868.1730 Oxygen Uptake

Computer

Device Class:

Class IIa

**Predicate Device:** Medgraphics Desktop Diagnostic System with 15% CO<sub>2</sub> Analyzer, K955432 manufactured by Medical Graphics Corporation, 350 Oak Grove Parkway, St. Paul, MN 55127.

**Description:** The Ultima system is a cardiopulmonary exercise system that provides breath by breath measurements of flow, oxygen uptake and carbon dioxide production.

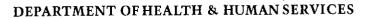
**Intended Use:** Medgraphics Ultima system is intended for medical applications requiring a non-invasive assessment of the cardiopulmonary response to exercise or measurement of energy expenditure using indirect calorimetry.

**Comparison:** Direct comparison with the predicate device was made with acceptable conclusions.

**Discussion:** Laboratory testing of 11 systems has shown the Ultima system to have substantial equivalence in performance and precision to the predicate device. Tandem gas exchange system validator studies performed with the predicate device produced comparative data output with less than 3% variability for VO<sub>2</sub>, VCO<sub>2</sub> and tidal volume.

**Conclusion:** The Medgraphics Ultima system is substantially equivalent to the predicate device.

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Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

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Medical Graphics Corp. c/o Ms. Lynn Brosious **Ouality and Regulatory Affairs** 350 Oak Grove Parkway St. Paul, MN 55127

Re: K061731

Trade Name: MedGraphics Ultima System Regulation Number: 21 CFR 868.1730 Regulation Name: Oxygen Uptake Computer

Regulatory Class: Class II (two)

Product Code: BZL Dated: August 28, 2006 Received: August 28, 2006

#### Dear Ms. Brosious:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

### Page 2 – Ms. Lynn Brosoius

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>.

Sincerely yours,

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Gimmuma for

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## **Indications for Use**

510(k) Number (if known): K 06/73/

**Device Name: Medgraphics Ultima System** 

# **Indications for Use:**

The Ultima system uses the direct measurement of oxygen uptake to objectively and non-invasively assess cardiac and pulmonary function during exercise. The system can be used to screen for early signs of cardiac and pulmonary dysfunction; differentiate heart and lung disease; assess dyspnea complaints; classify patients according to severity of disease as a guide for patient management; establish an optimal exercise prescription and training program; evaluate the efficiency of prescribed therapy.

The Ultima system uses the direct measurement of oxygen uptake and carbon dioxide production to provide nutritional assessment, to optimize nutritional supplements and quantify substrate utilization.

The Ultima system can also provide direct Fick determination of cardiac output using real time oxygen uptake measurements.

| Prescription Use _ | _X     | AND/OR | Over the Counter use   |  |
|--------------------|--------|--------|------------------------|--|
| (Part 21 CFR 801   | Subpar | t D)   | (21 CFR 801 Subpart C) |  |

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(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K 06(73)